

§ 12.3

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States of food, drugs, devices, cosmetics, and tobacco products as defined in section 201 (f), (g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (f), (g), (h), (i)) is governed by section 801 of the Act, as amended (21 U.S.C. 381) and regulations issued under authority of section 701(b) of the Act (21 U.S.C. 371(b)) by the Secretary of Health and Human Services and the Secretary of the Treasury (21 CFR 1.83 through 1.99).

(b) *Federal Insecticide, Fungicide, and Rodenticide Act.* The importation of pesticides and devices is governed by section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136o(c)), and regulations issued under the authority of section 17(e) of that Act (7 U.S.C. 1360(e)) by the Secretary of the Treasury, in consultation with the Administrator of the Environmental Protection Agency, as set forth below (§12.110 *et seq.*).

(c) *Federal Hazardous Substances Act.* The importation of hazardous substances, misbranded hazardous substances, or banned hazardous substances as defined in section 2 of the Federal Hazardous Substances Act, as amended (15 U.S.C. 1261), is governed by regulations issued under the authority of sections 10(b) and 14 of the Act, as amended (15 U.S.C. 1269, 1273), by the Consumer Product Safety Commission (16 CFR 1500.265 through 1500.272).

[T.D. 68–191, 33 FR 11019, Aug. 2, 1968, as amended by T.D. 75–194, 40 FR 32321, Aug. 1, 1975; T.D. 82–145, 47 FR 35475, Aug. 16, 1982; CBP Dec. 10–29, 75 FR 52450, Aug. 26, 2010]

§ 12.3 Release under bond; liquidated damages.

(a) *Release.* No food, drug, device, cosmetic, tobacco product, pesticide, hazardous substance or dangerous caustic or corrosive substance that is the subject of §12.1 will be released except in accordance with the laws and regulations applicable to the merchandise. When any merchandise that is the subject of §12.1 is to be released under bond pursuant to regulations applicable to that merchandise, a bond on Customs Form 301, containing the bond conditions set forth in §113.62 of this chapter, will be required.

(b) *Bond amount.* The bond referred to in paragraph (a) of this section must be

in a specific amount prescribed by the port director based on the circumstances of the particular case that is either:

(1) Equal to the domestic value (see §162.43(a) of this chapter) of the merchandise at the time of release as if the merchandise were admissible and otherwise in compliance; or

(2) Equal to three times the value of the merchandise as provided in §113.62(m)(1) of this chapter.

(c) *Liquidated damages.* Whenever liquidated damages arise with regard to any food, drug, device or cosmetic subject to §12.1(a) for failure to redeliver merchandise into Customs custody or for failure to rectify any noncompliance with the applicable provisions of admission, including the failure to export or destroy the merchandise within the time period prescribed by law after the merchandise has been refused admission pursuant to the provisions of the Food, Drug and Cosmetic Act, those liquidated damages will be assessed pursuant to §113.62(m)(1) of this chapter in the amount of the bond prescribed under paragraph (b) of this section.

[T.D. 01–26, 66 FR 16853, Mar. 28, 2001; CBP Dec. 08–46, 73 FR 71780, Nov. 25, 2008; CBP Dec. 10–29, 75 FR 52451, Aug. 26, 2010]

§ 12.4 Exportation.

The exportation of merchandise, the subject of §12.1, refused admission into the United States in accordance with regulations applicable thereto shall be under Customs supervision in accordance with the regulations set forth in §§18.25 and 18.26 of this chapter.

[T.D. 68–191, 33 FR 11019, Aug. 2, 1968]

§ 12.5 Shipment to other ports.

When imported merchandise, the subject of §12.1, is shipped to another port for reconditioning or exportation, such shipment shall be under a Customs carrier's manifest, Customs Form 7512, in the same manner as shipments in bond.

[T.D. 68–191, 33 FR 11019, Aug. 2, 1968]

IMPORTATION OF CERTAIN CHEESES

§ 12.6 Affidavits required to accompany entry.

(a) Cheeses produced in the member states of the European Communities shall not be permitted entry into the Customs territory of the United States (excluding Puerto Rico) if exported from any country or area other than the country of origin, or into Puerto Rico, unless accompanied by:

(1) An affidavit, in the event of shipments into the Customs territory of the United States (excluding Puerto Rico), of the producer or exporter that the cheese has not received and will not receive restitution payments of the type referred to in Executive Order No. 11851, dated April 10, 1975 (40 FR 16645); or

(2) An affidavit, in the event of shipments into Puerto Rico, of the importer that the cheese will be consumed in Puerto Rico or areas outside the Customs territory of the United States. Proof of actual consumption shall be furnished to the appropriate Customs officer within three years after the date such cheese is entered or withdrawn from warehouse, for consumption.

(b) These affidavits shall not be required to accompany importations of cheese produced in the member states of the European Communities if such cheese is shipped directly to the United States (excluding Puerto Rico) from the country of origin on a through bill of lading.

[T.D. 75-210, 40 FR 36767, Aug. 22, 1975]

MILK AND CREAM

§ 12.7 Permits required for importation.

(a) Under the Act of February 15, 1927 (44 Stat. 1101, as amended, 21 U.S.C. 141-149), commonly known as the Federal Import Milk Act, the importation into the United States of milk and cream is prohibited unless the person by whom such milk or cream is shipped or transported into the United States holds a valid permit from the Department of Health and Human Services. Such permits become invalid at the end of one year unless applications for

renewal are filed prior to the date of expiration.

(b) The regulations of the Department of Health and Human Services under the said act require that each container of milk or cream shipped or transported into the United States by a permittee shall have firmly attached thereto a tag showing in clear and legible type the product (raw milk, pasteurized milk, raw cream, or pasteurized cream) the permit number and the name and address of the shipper; except that in case of unit shipments consisting of milk only or cream only under one permit number, each container need not be so marked if the vehicle of transportation is sealed and tagged with the above-mentioned tag. In such case the tag is required to show, in addition to the other required information, the number of containers and the contents of each. Customs officers shall not permit the importation of any milk or cream that is not tagged in accordance with such regulations.

[28 FR 14710, Dec. 31, 1963, as amended by T.D. 82-145, 47 FR 35475, Aug. 16, 1982; T.D. 89-1, 53 FR 51253, Dec. 21, 1988]

MEAT AND MEAT-FOOD PRODUCTS

§ 12.8 Inspection; bond; release.

(a) All imported meat and meat-food products offered for entry into the United States are subject to the regulations prescribed by the Secretary of Agriculture under the Animal Health Protection Act. (7 U.S.C. 8301, *et seq.*). The term "meat and meat-food products," for the purpose of this section, shall include any imported article of food or any imported article which enters or may enter into the composition of food for human consumption, which is derived or prepared in whole or in part from any portion of the carcass of any cattle, sheep, swine, or goat, if such portion is all or a considerable and definite portion of the article, except such articles as organotherapeutic substances, meat juice, meat extract, and the like, which are only for medicinal purposes and are advertised only to the medical profession. Such meat and meat-food products will not be released from CBP custody prior to inspection by an inspector of the Food Safety and Inspection Service, Meat